UNITED
NATIONS

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Economic and Social Council

Distr.
LIMITED

E/ICEF/1993/L.3
16 February 1993

ORIGINAL: ENGLISH

UNITED NATIONS CHILDREN'S FUND
Programme Committee
1993 session

FOR INFORMATION

PROGRESS REPORT ON THE CHILDREN'S VACCINE INITIATIVE

SUMMARY

The Children's Vaccine Initiative began its second year with a successful consultative group meeting in Geneva. The initiative is moving forward with two main areas of activity: facilitating the analysis of the global production, distribution and utilization of vaccines containing diphtheria, pertussis, tetanus, poliomyelitis, measles and tuberculosis antigens and concurrently assuring adequate, affordable and high-quality vaccines for use in developing countries; and developing, testing and introducing new vaccines for the global immunization programme.

The analysis of the current use of vaccines has provided a guide for prioritizing support to developing countries and utilizing donor resources most effectively to assist local production, co-production or importation of vaccines to meet the needs of all countries. Support for quality control and improving production capacity has begun for 10 selected countries, which account for 56 per cent of the developing world's children. The Vaccine Independence Initiative revolving fund has been capitalized and countries have begun to use this facility to procure vaccines through the UNICEF supply system.

A task force has outlined four priorities for vaccine research and development: developing multi-antigen vaccines built on the combined diphtheria/pertussis/tetanus (DPT) vaccine; improving heat stability, with an emphasis on the poliomyelitis vaccine; developing micro-encapsulation technology to deliver several doses over time through one injection (initially using tetanus toxoid vaccine); and improving measles vaccines to allow for child immunization earlier in life.

The haemophilus influenza B vaccine is being tested for use against pneumonia in tropical environments and is likely to be combined with DPT for global use.

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INTRODUCTION

1. The Children's Vaccine Initiative was organized jointly by the World Health Organization (WHO), UNICEF, the United Nations Development Programme (UNDP), the World Bank and the Rockefeller Foundation to enhance collaboration among national immunization programmes, research organizations, international donors and the vaccine manufacturing industry. Its purpose is to develop, test, license and produce new and improved vaccines in order to immunize against a larger number of diseases and to increase the efficiency and ease of immunizing children.

2. In September 1991, the Director-General of WHO and the Executive Director of UNICEF, in a special ceremony with the Secretary-General of the United Nations, announced that the 1990 goal of 80 per cent immunization coverage of infants had been achieved and that 100 million infants had been vaccinated during 1990. At its 1992 session, the Executive Board acknowledged this achievement and the key role of UNICEF in the success of the effort, and stressed the need to sustain and improve the level of achievement to protect children against the scourge of measles, neonatal tetanus, poliomyelitis and other vaccine-preventable diseases. The Board approved UNICEF participation in the Children's Vaccine Initiative and requested that the organization focus its participation on: (a) strengthening the vaccine delivery system through targeted operations research in cold-chain and sterilization management and through increasing the integration of immunization delivery with other key maternal and child health interventions; (b) assuring the availability of low-cost, high-quality vaccines; (c) supporting the development of effective disease surveillance systems designed to measure the impact of immunization; and (d) facilitating the introduction of new and improved vaccines into the expanded programme on immunization (EPI) through appropriate studies.

3. As a multi-agency endeavour, the Children's Vaccine Initiative includes four management bodies: a standing committee represented by the five founding agencies; a 30-member management advisory committee; a consultative group which represents all participating organizations; and a secretariat. Operational activities are carried out by product development groups and task forces. Special efforts have been made to enhance the level of collaboration between the private and public sectors and to link vaccine research and development with the delivery of vaccines. The consultative group met in November 1992, reviewed the work of the product development groups and the task forces, and provided guidance for the development of a strategic plan for the Initiative.

4. The experience of the past two years has demonstrated that the successful development of new and improved vaccines is not merely a research project, but is rather a process that should build on the experience of current vaccine use in the global immunization programme. Cost and quality of vaccines have become the two most critical issues, as prices from international suppliers have escalated and the effectiveness of vaccines produced in some developing countries has been uncertain. Consequently the Children's Vaccine Initiative will continue to develop, support and facilitate progress along two parallel tracks: building capacity and systems to assure high-quality, affordable vaccines for EPI in developing countries; and promoting and coordinating research and development for new and improved vaccines.

I. ASSURING VACCINES FOR THE EXPANDED PROGRAMME ON IMMUNIZATION

5. During the past decade UNICEF, WHO, Rotary International, bilateral donors and several developing countries have been successful in providing adequate quantities of high-quality vaccines to meet the EPI requirements in developing countries. However, during the past year the provision of adequate vaccines to meet the goal of disease eradication and the continued expansion of EPI have been problematic due to three factors: higher prices; increasing volume requirements; and a shrinking resource base.

6. A task force organized by the Children's Vaccine Initiative has conducted an analysis of the global vaccine situation. Preliminary data show that more than one half of vaccines used in developing countries are produced domestically. The task force developed a general strategy for assuring vaccines for developing countries based on three factors: population; wealth; and technical capacity. The largest countries, which have adequate technical capacity, will be supported in domestic vaccine production; middle-income countries will be assisted in vaccine procurement; and the poorest countries will continue to receive donated vaccines for the next several years, although all countries are encouraged to provide at least a portion of the resources for the purchase of vaccines. The elaboration and implementation of this general strategy have already begun. A more detailed survey of projected vaccine requirements and utilization, source of vaccines used (local production or imported) and source of funding for vaccines is under way. Teams of experts in vaccine production and quality control are visiting countries that will produce vaccines domestically. The teams have already visited Bangladesh, China, Egypt and Viet Nam, and will visit Brazil, India, Indonesia, Mexico, Pakistan and the Philippines during the first half of 1993. They are to assess both quality control and production capacity and recommend a plan to increase production levels to meet national requirements and to ensure that vaccines meet WHO quality requirements. Specific proposals for donor support for each country will be submitted for funding by interested donors. These activities are being carried out jointly by the Vaccine Situation Analysis and Quality Control Task Forces, with operational support provided by UNICEF and WHO.

7. The Vaccine Independence Initiative, managed by UNICEF, also began operation in 1992. This initiative provides developing countries with access to a revolving fund and the UNICEF procurement system to support the procurement of vaccines from government budgets. The Government of Morocco entered into this mechanism in December 1992 and will pay for all vaccine needs with local currency. UNICEF will utilize local currency for country programme activities and reimburse the revolving fund, which was initially capitalized by the United States Agency for International Development. More than 10 other countries have expressed an interest in joining this scheme and all efforts will be made to facilitate their entry during 1993.

II. STRENGTHENING EPIDEMIOLOGICAL CAPACITY

8. A task force has been established to strengthen epidemiological capacity and disease surveillance. This task force will help to develop regional networks and national disease surveillance systems. It has begun to develop a work plan to guide the use of disease surveillance to assess the efficacy of vaccines and the integrity of the cold chain. Epidemiologists from France, the United Kingdom of Great Britain and Northern Ireland, the United States of America and other countries have begun collaboration with WHO and UNICEF to strengthen developing country capacity to manage effective systems for the eradication of poliomyelitis, the elimination of neonatal tetanus and the control of measles and other diseases. Surveys in some countries have revealed failure due to problems in vaccine quality or vaccine handling. These problems are being addressed by the respective Governments, with support from UNICEF, WHO and other Children's Vaccine Initiative donors.

III. PRIORITIES FOR VACCINE RESEARCH AND DEVELOPMENT

9. A task force was organized to review possible vaccine research and to recommend to the management advisory committee priorities for action and investment. Twelve bacterial and viral vaccines were selected from a list of more than 50 for review by the task force during the first year. The criteria for ranking of priority were as follows: the disease must be widespread; and the vaccine must need improvement and must be either an EPI vaccine, a licensed non-EPI vaccine or an unlicensed vaccine likely to be available within five years. Papers were prepared outlining such relevant issues as the epidemiology and disease burden, science and technology, scale-up and production, special regional problems and potential cost-effectiveness for each vaccine.

10. The task force selected three vaccines for priority attention - pneumococcus, haemophilus influenza B and hepatitis B - to be used individually or together with the combined diphtheria/pertussis/tetanus vaccine. Other priorities were a heat-stable poliomyelitis vaccine, controlled release tetanus toxoid vaccine and measles vaccine that can be administered safely and effectively to infants under nine months of age. The characteristics of an ideal children's vaccine are heat stability, minimum number of doses given early in life and inclusion of multi-antigens. Each of the above priority activities deals with one of these characteristics; thus, each activity will provide incremental basic and applied scientific information and become a building block in reaching the ultimate goal of producing a single-dose, heat-stable, multi-antigen vaccine that can be given shortly after birth.

A. Heat-stable poliomyelitis vaccine

11. The objective of the product development group for the poliomyelitis vaccine is to improve the stability of the Sabin oral poliomyelitis vaccine so that it can withstand exposure to 45 degrees Celsius for seven days with a drop in potency of less than one half log. In simple terms, the goal is to be able to carry the vaccine for one week in one's pocket without the protection of a cold chain. This will greatly enhance the possibility of eradicating poliomyelitis by the target date of the year 2000. Two basic strategies are

being used: organic stabilizers and innovative drying techniques. Preliminary results will be available early in 1993. The next phase will include limited clinical testing.

B. Single-dose tetanus toxoid vaccine

12. The goal of this research is to encapsulate tetanus toxoid into microspheres prepared from copolymers of lactic and glycolic acids, which will allow for controlled release of the toxoid into the body and thereby simulate multiple booster injections of the currently used tetanus toxoid vaccine. Five properly spaced doses are required to provide lifetime protection.

13. Success in this endeavour will require extensive collaboration with the private sector. This will be facilitated through the International Federation of Pharmaceutical Manufacturers. Four laboratories are currently collaborating with the product development group in this project.

C. Measles vaccine

14. Measles continues to be a major killer of young children, in part because the vaccines used currently are unable to overcome the shield of maternal antibodies if given earlier than nine months of age. Attempts have been made to increase the potency of vaccines to enable them to be administered at six months of age; however none has proven to be both safe and effective. A special task force of measles vaccine experts was convened to recommend a strategy for research and development that will establish a scientific base regarding neonatal immunity and will develop, test and produce a new generation of measles vaccines. The report of the task force was prepared in February of this year. Studies are being implemented by the WHO EPI to assess the efficacy of two-dose schedules for measles control and eventual eradication.

IV. COLLABORATION AMONG DEVELOPMENT PARTNERS

15. The pharmaceutical industry will play a significant role in the development and production of new vaccines, which must be affordable enough for use in developing countries. The industry has shown a considerable interest in the Children's Vaccine Initiative and has frequently called for effective cooperation in order to facilitate the efficient development, testing and licensing of vaccines. However, developing countries need affordable vaccines and will require some leverage to maintain low prices. A task force is working on this set of issues as well as on intellectual property rights.

16. Many agencies and organizations are investing tens of millions of dollars in vaccine research. It has been estimated that $1 billion is expended annually in developing countries for immunization programmes. The activities of the Children's Vaccine Initiative are of two kinds: those funded and managed by the participating agency and those funded and managed by the Initiative's product development groups or task forces. Expenditures for the latter were $3.8 million in 1992. Projected expenditures for 1993 have been

set at $6.4 million. Contributors to date have been the Agency for Cooperation in International Health (Japan), the Canadian International Development Agency, the Rockefeller Foundation, Rotary International, UNICEF, UNDP and WHO. The Children's Vaccine Initiative secretariat, with support from UNICEF and WHO, is preparing project proposals for submission to donor agencies and other partners. During 1992, UNICEF funds were utilized in a catalytic manner to support the core budget, with the other sponsoring agencies, and to support activities of the several task forces and product development groups. The request for continued UNICEF support for the biennium 1994-1995 is included in the global funds programme budgets (E/ICEF/1993/P/L.3).